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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------------|---------------------|------------------|
| 10/758,415 | 01/16/2004 | William S. Brusilow | 2930-109 | 5654 |
| 6449 7590 06/11/2009 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005 | | | | |
| EXAMINER VAKILL, ZOIREH | | | | |
| ART UNIT 1614 | | PAPER NUMBER | | |
| NOTIFICATION DATE 06/11/2009 | | DELIVERY MODE ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/758,415

Applicant(s)

BRUSILOV, WILLIAM S.

Examiner

ZOHREH VAKILI

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 and 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10, 11 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-20 are presented for examination.

The Finality of the action, mailed May 5, 2008 is hereby withdrawn. Notice of Appeal is moot in view of new grounds of rejection.

Applicant's Amendment and arguments filed February 13, 2009 has been received and entered into the present application.

Applicant's arguments, filed February 13, 2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 10-11, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Apostolakis et al., Brain Research Bulletin, or Ginefri-Gayet et al.,

Pharmacology Biochemistry and Behavior, in view of Liedtke et al. (US Pub. No. 20030013650 A1), and further in view of Feurerstein et al. (US Pub. No. 20020173537 A1).

Apostolakis teaches methionine sulfoximine (MSO) is a centrally acting neurotoxin with convulsive properties; it has been used in study of epilepsy. MSO suppresses the formation of glutamine (see page 257, col. 1, first paragraph). Apostolakis further teaches pharmaceutical unit doses in an amount of methionine sulfoxime of 2 mg/ml normal saline and 200 micro gram/100 micro liter administered intravenously (IV) and intracerebroventricularly (IVT). The animals were sacrificed at different times after MSO administration (see page 257, column 2).

Ginefri-Gayet teaches pharmaceutical unit doses in an amount of methionine sulfoxime of 50-75 micro gram/10 micro liters. See page 174, column 2, under ICV Injection of MSO.

Liedtke teaches that the present invention relates to the identification in vertebrate animals including humans, of an ion channel for rapid conduction of cations, among them, Ca^{2+} . This ion channel, named VR-OAC, demonstrates activity as an osmoreceptor, and also demonstrates a role in mechanical stimulation and responsiveness (see page 1, paragraph 2). VR-OAC is expressed in nerve-cells of the hippocampus, CA1 region, a region of importance for memory and in epileptic seizures (page 6, paragraph 89). Liedtke further teaches that the recombinant protein can be refolded prior to or after cleavage to form a functionally active polypeptide. Suitable redox (reducing/oxidizing) agent pairs include, but are not limited to, reduced

glutathione/glutathione disulfide, cystine/cysteine, cystamine/cysteamine (see page 16, paragraph 203). Mammalian expression vectors contemplated for use in the invention include vectors with inducible promoters, such as, a glutamine synthetase/methionine sulfoximine co-amplification vector, (see page 16, paragraph 207), which reads on claims 10 and 11.

Feurerstein et al. teach of a compound treating neurodegenerative diseases including polyglutamine diseases (see page 1, paragraph 0003). The composition is useful for treating a polyglutamine disease e.g. Huntington's disease, dentorubropallidolusian atrophy, spinal and bulbar muscular atrophy, spinocerebellar ataxis (SPA -1, -2, -3, -6, -7), and acute and chronic glaucoma. Also the compounds are useful for treating disorders of central nervous system e.g. stroke, hypoglycemia, hypoxia, trauma, epilepsy, Alzheimer's disease, AIDS-associated dementia, amyotrophic lateral sclerosis, Parkinson's disease and chronic alcoholism (see page 2, paragraph 0030).

Clearly, the skilled artisan is provided with ample instruction and motivation to use MSO in the treatment of neurodegenerative diseases including polyglutamine diseases. The skilled artisan is motivated to make compositions of the well known ingredients used in applications for treatment of polyglutamine diseases. The prior art teach of the same component and its concentration that is instantly claimed. Accordingly, it is well settled that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure that is

used to treat one disease, therefore will treat another disease from the same family as taught by Feurerstein et al., the properties applicant discloses and/or claims are necessarily present. In other words, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach and suggest the invention as claimed. Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Thus in the absence of evidence to the contrary, the invention of claims 1-5, 10-11, and 21 would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims of the present application are allowed.

Any inquiry concerning this communication should be directed to Zohreh Vakili, telephone number 571-272-3099. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m., Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili
Patent Examiner
Art Unit 1614

June 4, 2009

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614